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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION and NOVARTIS AG, Plaintiffs, v. WOCKHARDT USA LLC; and WOCKHARDT LTD., Defendants.	Civil Action No. 12-3967 (SDW)(MCA) (CONSOLIDATED) **HIKMA FARMACEUTICA S.A.'S ANSWER TO NOVARTIS'S COMPLAINT**
NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION, and NOVARTIS AG, Plaintiffs, v. SUN PHARMA GLOBAL FZE and SUN PHARMACEUTICAL INDUSTRIES LIMITED, Defendants.	Civil Action No. 12-4393 (SDWHMCA) (Consolidated with Civil Action No. 12-3967)

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ACTAVIS LLC; APOTEX, INC.; APOTEX CORP.; GLAND PHARMA LTD.; DR. REDDY'S LABORATORIES, INC.; DR. REDDY'S LABORATORIES LTD.; EMCURE PHARMACEUTICALS USA, INC.; EMCURE PHARMACEUTICALS, LTD.; HOSPIRA, INC.; PHARMACEUTICS INTERNATIONAL INC.; SAGENT PHARMACEUTICALS, INC.; ACS DOBFAR INFO S.A.; STRIDES, INC.; AGILA SPECIALTIES PRIVATE LTD.; SUN PHARMA GLOBAL FZE; CARACO PHARMACEUTICAL LABORATORIES, LTD.; SUN PHARMACEUTICAL INDUSTRIES LTD.; WOCKHARDT USA LLC; and WOCKHARDT LTD., Defendants.	Civil Action No. 13-1028 (SDW)(MCA)
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ACCORD HEALTHCARE INC.; FRESENIUS KABI USA, LLC; and HIKMA FARMACEUTICA S.A., Defendants.	Civil Action No. 13-2379 (SDW)(MCA)

Defendant Hikma Farmaceutica S.A. ("Hikma"), by and through its undersigned counsel, files this Answer, Affirmative Defenses, and Counterclaims to Plaintiff Novartis Pharmaceuticals Corporation's Complaint, and in support thereof states as follows:

ANSWER

1. Plaintiff Novartis Pharmaceuticals Corporation ("Novartis") alleges as follows on personal knowledge as to its own actions and observations, and on information and belief as to all other facts.

Answer

Hikma lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies the allegations on that basis.

NATURE OF THE ACTION

2. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 that arises out of Defendants' request for approval from the U.S. Food and Drug Administration ("FDA") to manufacture and sell generic versions of Novartis' Zometa® product prior to expiration of U.S. Patent No. 8,324,189 ("the '189 patent"), which is directed to oncology methods.

Answer

Hikma admits that the claims alleged in the Complaint arise under the patent laws of the United States and the Declaratory Judgment Act. Hikma further admits that it is seeking FDA approval to manufacture and sell a generic version of a Zometa® product prior to expiration of U.S. Patent No. 8,324,189 ('the '189 patent"). Hikma lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations and therefore denies the remaining allegations on that basis.

THE PARTIES

A. Novartis

3. Plaintiff Novartis is a corporation organized under Delaware law. Its principal place of business is in East Hanover, New Jersey. Novartis owns the '189 patent.

Answer

Hikma lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies the allegations on that basis.

B. Accord Healthcare Inc.

4. Accord Healthcare Inc. ("Accord") is a corporation organized under North Carolina law. Its principal place of business is 1009 Slater Road, Suite 210-B, Durham, North Carolina, 27703. Upon information and belief, Defendant Accord has systematic and continuous contacts with New Jersey, including engagements to strategically develop, market, deliver, and/or sell generic products in New Jersey. In addition, Defendant Accord has previously acquiesced to personal jurisdiction and asserted counterclaims in this District.

Answer

Hikma lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies the allegations on that basis.

5. Upon information and belief, Defendant Accord has submitted to the FDA ANDA No. 205279, seeking approval to market a generic version of Zometa.

Answer

Hikma lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies the allegations on that basis.

C. Hikma Farmaceutica S.A.

6. Hikma Farmaceutica S.A. ("Hikma") is a corporation chartered under the laws of the Republic of Portugal. Its principal place of business is Estrada Rio Da Mo No. 8, 8[a] & 8b-Fervenca, 2705-906 Terrugem SNT, Portugal. Upon information and belief, Defendant Hikma has systematic and continuous contacts with New Jersey, including engagements to strategically develop, market, deliver, and/or sell generic products in New Jersey. In addition, Defendant

Hikma's agent and subsidiary, West-Ward Pharmaceutical Corp., through which, upon information and belief, Defendant Hikma conducts its U.S. operations, is located in this District. Defendant Hikma has also previously asserted claims in this District.

Answer

The allegations state legal conclusions to which no answer is required. To the extent any answer is required, Hikma admits that it is a corporation chartered under the laws of the Republic of Portugal with a principal place of business at Estrada Rio Da Mo No. 8, 8A/B-Fervenca, 2705-906 Terrugem SNT, Portugal. Hikma admits that West-Ward Pharmaceutical Corp. is located in New Jersey. Hikma further admits it has previously asserted claims in this District. Hikma denies the remaining allegations.

7. Upon information and belief, Defendant Hikma has submitted to the FDA ANDA No. 202182, seeking approval to market a generic version of Zometa.

Answer

Admitted.

D. Fresenius Kabi USA, LLC

8. Fresenius Kabi USA, LLC ("Fresenius" and, together with Defendants Accord and Hikma, "Defendants") is a Delaware limited liability company. Its principal place of business is 1501 East Woodfield Road, Suite 300 East Schaumburg, Illinois 60173-5837. Upon information and belief, Defendant Fresenius has systematic and continuous contacts with New Jersey, including engagements to strategically develop, market, deliver, and/or sell generic products in New Jersey.

Answer

Hikma lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies the allegations on that basis.

9. Upon information and belief, Defendant Fresenius has submitted to the FDA ANDANo. 091516, seeking approval to market a generic version of Zometa.

Answer

Hikma lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies the allegations on that basis.

JURISDICTION AND VENUE

10. This action seeks to enforce federal patent rights under federal law. Accordingly this Court has federal question jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and declaratory judgment jurisdiction under 28 U.S.C. §§ 2201 and 2202.

Answer

The allegations state legal conclusions to which no answer is required. To the extent any answer is required, Hikma admits that this Court has federal question jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). Hikma denies the remaining allegations.

11. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

Answer

The allegations state legal conclusions to which no answer is required. To the extent any answer is required, Hikma does not contest venue in this District for purposes of this action only.

12. This Court has personal jurisdiction over defendants for the following reasons, among others:

i. Defendants have sold generic drugs in New Jersey, and are seeking approval and/or have obtained tentative approval to sell and/or distribute a generic version of Zometa in New Jersey;

ii. Novartis, which will be harmed by Defendants' actions, is domiciled in New Jersey;

iii. Defendants have systematic and continuous contacts with New Jersey, in

that, among other things, they sell, manufacture, import and/or distribute generic drugs in New Jersey;

iv. Defendant Accord has previously acquiesced to personal jurisdiction and asserted counterclaims in this District; and

v. Defendant Hikma has previously asserted claims in this District.

Answer

The allegations state legal conclusions to which no answer is required. To the extent any answer is required, Hikma admits that it has previously asserted claims in this District. Hikma further states that it will not contest personal jurisdiction for purposes of this action only. Hikma denies the remaining allegations directed to it. Hikma lacks knowledge or information sufficient to form a belief about the truth of the allegations with respect to other defendants and therefore denies them.

STATEMENT OF FACTS

A. Novartis' Branded Products

13. The active ingredient in Zometa is zoledronic acid. Zometa was first approved by the FDA in 2001 and is used to treat hypercalcemia of malignancy (HCM), a condition resulting in high calcium blood levels due to cancer, multiple myeloma and bone metastases from solid tumors. Zometa's primary indication is for the prevention of skeletal-related complications associated with cancer, such as fractures and pain.

Answer

Hikma admits that the active ingredient in Zometa is zoledronic acid and that Zometa is approved for the indications listed in the current FDA-approved labeling. Hikma lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations and therefore denies the remaining allegations on that basis.

14. Zometa is administered intravenously as a 4 mg dose of zoledronic acid diluted in standard buffer media. Zometa has been sold in three forms: (a) a "pre-concentrate" vial of 4 mg of Zometa diluted in 5 mg of buffer, which must be further diluted before administration to a

patient; (b) a "Ready to Use" or "RTU" vial of 4 mg of Zometa in fully diluted form; and (c) a 4 mg vial of powder, which would be diluted by an infusion center before administration to a patient (this product was discontinued in 2003). Unopened, Zometa has a shelf life of three years.

Answer

Hikma admits that Zometa is administered intravenously and that it has been approved in a pre-concentrate vial form that contains 4 mg of zoledronic acid in 5 ml of solution, and in an RTU form that contains 4 mg of zoledronic acid. Hikma lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations and therefore denies the remaining allegations on that basis.

B. The Patent-In-Suit

15. The '189 patent, entitled "Use of zolendronate for the manufacture of a medicament for the treatment of bone metabolism diseases," was duly and legally issued on December 4, 2012, and is owned by Novartis. During clinical trials of Zometa, Novartis scientists learned that cancer patients could suffer renal toxicity – *i.e.*, kidney damage – if the drug were administered too quickly. After extensive clinical experimentation, however, Novartis scientists discovered that renal toxicity could be controlled if Zometa were administered as a 4 mg dose over a 15 minute period. The '189 patent is directed to this method of treatment. A copy of the '189 patent is attached as Exhibit 1.

Answer

Hikma denies that the '189 patent was attached to the Complaint as served on Hikma. Hikma admits that the '189 patent is entitled "Use of zolendronate for the manufacture of a medicament for the treatment of bone metabolism diseases," and that the face sheet of the patent indicates that it issued on December 4, 2012. Hikma lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations and therefore denies them.

16. Zometa and its methods of use are covered by one or more claims of the '189 patent, which has been listed in connection with Zometa in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is also referred to as the "Orange Book." Accordingly, Defendants have actual or constructive knowledge of the patent.

Answer

Hikma admits that the '189 patent is listed in the Orange Book for Zometa. Hikma also admits that it has knowledge of the '189 patent. Hikma denies the remaining allegations.

C. The ANDA Process

17. The FDA regulates the manufacture, sale and labeling of prescription drugs in the U.S. Under the 1984 Hatch-Waxman Act, companies wishing to bring a generic version of a branded prescription drug to market can submit an Abbreviated New Drug Application (ANDA) to the FDA. 21 U.S.C. § 355(j). This ANDA process allows the generic drug maker to avoid the expensive clinical trials required of an NDA holder to demonstrate a drug's safety and effectiveness. The generic company simply relies on the original NDA submission for that purpose.

Answer

The allegations state legal conclusions to which no answer is required. On that basis, Hikma denies the allegations .

18. The Hatch-Waxman Act also contains provisions meant to balance the interests of branded and generic companies in resolving claims concerning the branded company's patents. The Act requires drug makers to identify the patents covering their drugs in the Orange Book. 21 U.S.C. § 355(b)(1)(c)(2). When seeking ANDA approval, the applicant must take certain actions with respect to listed patents.

Answer

The allegations state legal conclusions to which no answer is required. On that basis, Hikma denies the allegations.

19. In particular, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), an applicant can assert that the branded drug's patent(s) is/are invalid, unenforceable, and/or will not be infringed, a so-called "Paragraph IV certification." Such a certification is provided to the FDA and notice is given to the NDA holder and patent owner. Upon receiving notice of the certification, the NDA holder or patent owner can choose to enforce its patents in federal court.

Answer

This paragraph states legal conclusions to which no answer is required. On that basis, Hikma denies the allegations.

D. Defendants' ANDA Applications

20. By letter dated March 14, 2013, Defendant Accord notified Novartis that it had submitted to the FDA ANDA No. 205279 for a generic version of Zometa ("Accord's ANDA Product").

Answer

Hikma lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies the allegations on that basis.

21. By letter dated March 25, 2013, Defendant Fresenius notified Novartis that it had submitted to the FDA ANDA No. 091516 for a generic version of Zometa ("Fresenius' ANDA Product").

Answer

Hikma lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies the allegations on that basis.

22. By letter dated April 3, 2013, Defendant Hikma notified Novartis that it had submitted to the FDA ANDA No. 202182 for a generic version of Zometa ("Hikma's ANDA Product" and, together with Accord's ANDA Product and Fresenius' ANDA Production, "Defendants' ANDA Products").

Answer

Admitted.

23. In their respective notice letters, Defendants stated that their ANDAs included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '189 patent and alleged that the '189 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, offer for sale or sale of the Defendants' ANDA Products.

Answer

Hikma admits that it notified Novartis that its ANDA includes a Paragraph IV certification asserting that the '189 patent is invalid, unenforceable and/or not infringed. Hikma lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations and therefore denies the remaining allegations on that basis.

24. This action is being commenced before expiration of forty-five days from Novartis' receipt of each of the notice letters.

Answer

Hikma admits that this action is commenced before expiration of forty-five days from Novartis' receipt of its notice letter. Hikma lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations and therefore denies the remaining allegations on that basis.

COUNT I (INFRINGEMENT OF THE '189 PATENT)

25. Each of the preceding paragraphs 1 to 24 is incorporated as if fully set forth herein.

Answer

Hikma repeats and incorporates its answers to Paragraphs 1 to 24 above.

26. Defendant Accord's submission of ANDA No. 205279 seeking to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic Zometa prior to expiration of the '189 Patent constitutes an act of infringement of one or more of the claims of the '189 patent under 35 U.S.C. § 271(e)(2)(A). Defendant Accord had knowledge of the '189 patent when it submitted its ANDA to the FDA.

Answer

Hikma lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies the allegations on that basis.

27. Defendant Fresenius' submission of ANDA No. 091516 seeking to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic Zometa

prior to expiration of the '189 Patent constitutes an act of infringement of one or more of the claims of the '189 patent under 35 U.S.C. § 271(e)(2)(A). Defendant Fresenius had knowledge of the '189 patent when it submitted its ANDA to the FDA.

Answer

Hikma lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies the allegations on that basis.

28. Defendant Hikma's submission of ANDA No. 202182 seeking to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic Zometa prior to expiration of the '189 Patent constitutes an act of infringement of one or more of the claims of the '189 patent under 35 U.S.C. § 271(e)(2)(A). Defendant Hikma had knowledge of the '189 patent when it submitted its ANDA to the FDA.

Answer

Hikma admits that it submitted a Paragraph IV certification in ANDA No. 202182 to obtain FDA approval to engage in the commercial manufacture, use, offer to sell, or sale of generic Zometa prior to expiration of the '189 patent. Hikma denies this act constitutes an act of infringement of the '189 patent under 35 U.S.C. § 271(e)(2)(A). Hikma denies that it had knowledge of the '189 patent when it submitted its ANDA to the FDA.

29. Upon information and belief, upon FDA approval of their respective ANDAs, Defendants will indirectly infringe the Zometa patent by making, using, offering to sell, and selling its zoledronic acid solution containing 4 mg zoledronic acid as the active ingredient in the United States and/or importing such a solution into the United States.

Answer

Hikma denies the allegations directed to it. Hikma lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations and therefore denies the remaining allegations on that basis.

30. Specifically, Defendants will knowingly and intentionally induce patients to infringe the '189 patent in violation of 35 U.S.C. § 271(b).

Answer

Hikma denies the allegations directed to it. Hikma lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations and therefore denies the remaining allegations on that basis.

31. Defendants will also contribute to infringement of the '189 patent by others, by knowingly offering to sell, selling, or distributing within the United States or importing into the United States generic Zometa, which has no substantial non-infringing uses, in violation of 35 U.S.C. § 271(c).

Answer

Hikma denies the allegations directed to it. Hikma lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations and therefore denies the remaining allegations on that basis.

32. There is an actual and justiciable case or controversy between Novartis and each of the Defendants concerning the validity and infringement of the '189 patent. Novartis is entitled to a declaration that Defendants' manufacture, use, sale, offer for sale, and/or importation of its generic Zometa drug product will contribute to the infringement of and/or actively will induce the infringement of one or more claims of the '189 patent, and that the claims of the '189 patent are valid.

Answer

The allegations state legal conclusions to which no answer is required. To the extent any answer is required, Hikma admits there is an actual and justiciable case or controversy between Novartis and Hikma concerning the validity and infringement of the '189 patent. Hikma denies the remaining allegations directed to it. Hikma lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations and therefore denies the remaining allegations on that basis.

PRAYER FOR RELIEF

WHEREFORE, Defendant Hikma denies that Plaintiff is entitled to any of the relief sought.

DEFENSES TO PLAINTIFF'S COMPLAINT

Without altering the burdens of proof, Hikma asserts the following affirmative and other defenses.

FIRST DEFENSE

Hikma will not directly, indirectly, contributorily, and/or by inducement infringe either literally or under the doctrine of equivalents any claim of the '189 patent under any section of 35 U.S.C. § 271.

SECOND DEFENSE

The claims of the '189 patent are invalid for failure to comply with 35 U.S.C. §§ 101, 102, 103, and/or 112.

THIRD DEFENSE

Novartis is misusing the '189 patent, which bars Novartis from any of the relief it seeks.

FOURTH DEFENSE

Novartis's claims are barred, in whole or in part, by the equitable doctrines of estoppel, waiver, and unclean hands.

FIFTH DEFENSE

Any additional defenses that discovery may reveal.

COUNTERCLAIMS

Hikma, for its Counterclaims against Novartis, alleges as follows:

1. Defendant and Counterclaim-Plaintiff Hikma is a corporation chartered under the laws of the Republic of Portugal, with its principal place of business located at Estrada Rio Da Mo No. 8, 8a & 8b – Fervenca, 2705-906 Terrugem SNT, Portugal.

2. Plaintiff Novartis is a corporation organized under Delaware law. Its principal place of business is in East Hanover, New Jersey. Novartis owns the '189 patent.

3. This is a declaratory judgment action under the patent laws of the United States, 35 U.S.C. § 1, *et seq.* Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

4. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and 1400(b).

5. This Court may declare the rights and legal relation for the parties pursuant to 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(e)(5).

6. Novartis has commenced the present action for patent infringement against Hikma in this Court. An actual and justiciable controversy therefore exists between the parties.

COUNT I – DECLARATORY JUDGMENT OF NONINFRINGEMENT '189 PATENT

7. Hikma incorporates by reference, as if fully set forth herein, the preceding paragraphs of its Answer and Counterclaim.

8. Hikma has not infringed and will not infringe any claim of the '189 patent, literally or under the doctrine of equivalents, either directly or indirectly, and has not induced infringement or contributed to infringement by others.

COUNT II – DECLARATORY JUDGMENT OF INVALIDITY '189 PATENT

9. Hikma incorporates by reference, as if fully set forth herein, the preceding paragraphs of its Answer and Counterclaim.

10. Each and every claim of the '189 patent is invalid for failure to comply with the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 for at least the reasons stated in Hikma's Notice Letter dated April 3, 2013.

11. Specifically, the claims of the '189 patent are invalid as anticipated and/or obvious over at least the following prior art references:

a. Berenson *et al. Proc. ASCO* 2000, 19:209a;

b. Body, *Cancer* 80(8):1699-1701 (1997);

c. Lipton *et al., Eur. J. Cancer* 35, Suppl. 4: S360 (1999);

d. Major *et al., Proc. ASCO* 2000, 19:605A; and

e. *Drugs of the Future*, 25(3):259-268 (2000).

12. The claims of the '189 patent are invalid for lack of definiteness because the claims are insolubly ambiguous.

13. The claims of the '189 patent are invalid for lack of utility because they do no more than recite the natural phenomena of following conventional steps for administering zoledronic acid.

PRAYER FOR RELIEF

WHEREFORE, Hikma prays that the Court enter a judgment that:

A. Hikma has not infringed any claim of the '189 patent;

B. Each and every claim of the '189 patent is invalid;

C. Novartis is not entitled to injunctive relief;

D. Novartis takes nothing by this action;

E. This be declared an exceptional case under 35 U.S.C. § 285, and that Hikma be awarded its costs, including reasonable attorneys' fees; and

F. For such other relief as the Court deems just and proper.

Dated: June 6, 2013

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Attorneys for Hikma Farmaceutica S.A.

CERTIFICATE OF SERVICE

I hereby certify that on June 6, 2013, I caused to be electronically filed the foregoing *Hikma Farmaceutica S.A.'s Answer, Affirmative Defenses and Counterclaims to Plaintiff's Corrected Amended Complaint* with the Clerk of Court via CM/ECF. Notice of this filing will be sent by email to all parties by operation of the Court's electronic filing systems. Parties may access the filing through the Court's CM/ECF System.

/s/Philip L. Hirschhorn